K133208

510(k) Summary

Per 21 CFR §807.92

NOV 14 2013

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311 USA
Contact Name and Information	Maureen Sundeen Principal of Regulatory Affairs Phone: 763-494-2903 Fax: 763-494-2222 Email: sundeenm@bsci.com
Date Prepared	October 16, 2013
Proprietary Name	Interlock™ -35 Fibered IDC™ Occlusion System
Common Name	Vascular Embolization Devices
Classification	Class II per 21 CFR 870.3300 Product Code: KRD Review Panel: Cardiovascular
Predicate Device	Interlock™ -35 Fibered IDC™ Occlusion System (K113651, January 11, 2013)

Intended Use / Indications for Use

The Interlock-35 Fibered IDC Occlusion System is indicated for obstructing or reducing blood flow in the peripheral vasculature during embolization procedures. This device is not intended for neurovascular use.

Device Description

The Interlock - 35 Fibered IDC Occlusion System includes a coil manufactured from platinum-tungsten alloy that is mechanically attached to a coil delivery wire. This assembly is contained within an introducer sheath. The platinum coil contains synthetic fibers for greater thrombogenicity. The Interlock - 35 Fibered IDC Occlusion System is designed to be delivered under fluoroscopy through a 5F (1.70 mm) OD (0.035 in [0.89 mm] or 0.038 in [0.97 mm] inner lumen) Imager™ II Selective Diagnostic Catheter without side flushing holes. The interlocking delivery wire design allows the coil to be advanced and retracted before final placement in the vessel, thus aiding in more controlled delivery including the ability to withdraw the coil prior to deployment.

Comparison of Technological Characteristics

The Interlock-35 Fibered IDC Occlusion System is similar in fundamental design, function, device materials, packaging, sterilization, operating principle, intended use / indication for use and fundamental technology as the predicate device. The modifications from the predicate device include changes to the coil, delivery wire, introducer sheath and carrier hoop design and materials for added pushability, deliverability, and to facilitate coil hydration. In addition, the DFU will provide instructions for flushing the device using the hand-injection setup which is an additional method for hydrating the coil.

Performance Data

The following bench testing was conducted for design elements and performance characteristics deemed appropriate to demonstrate equivalence to the predicate device. The Interlock-35 Fibered IDC Occlusion System met the predetermined acceptance criteria ensuring substantial equivalence to the predicate device. No new safety or performance issues were raised during testing.

- Interlocking Arm to Delivery Wire Tensile Strength
- Delivery Wire Bend Resistance
- Introducer Sheath Deliverability
- Device Preparation
- Corrosion Resistance
- Device Removal From Carrier Tube
- Sterilization
- Biocompatibility

Conclusion

Boston Scientific has demonstrated that the modification made for the Interlock-35 Fibered IDC Occlusion System are substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization, operating principle, and intended use / indication for use as the predicate device, Interlock-35 Fibered IDC Occlusion System (K113651).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 14, 2013

Boston Scientific Corp.
Maureen Sundeen
Principal of Regulatory Affairs
One Scimed Place
Maple Grove, MN 55311-1566 US

Re: K133208
Trade/Device Name: Interlock-35 Fibered IDC Occlusion System
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Devices
Regulatory Class: Class II
Product Code: KRD
Dated: October 16, 2013
Received: October 18, 2013

Dear Ms. Sundeen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133208

Device Name: Interlock™ -35 Fibered IDC™ Occlusion System

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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